

## REMARKS

Claims 1-4 are currently pending. Claims 3 and 4 are new, and are supported by the specification and claims as originally filed, for example, at page 20, paragraph 50. No new matter is added by way of this amendment.

### **I. Rejection Under 35 U.S.C. § 103(a)**

Claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,022,551 (to Jampani et al.) and U.S. Patent No. 5,965,610 (to Modak et al) in view of U.S. Patent No. 5,516,510 (to Beilfuss et al.). According to the Examiner, Jampani describes a composition comprising antimicrobial agents such as chlorhexidine digluconate (0.1-4.0%) and benzalkonium chloride (0.02-1.0%), among others, which are effective against gram negative and gram positive microorganisms when applied as a topical composition. The Examiner contends that Modak discloses an irritant-inactivating composition comprising an antimicrobial, such as, for example, benzalkonium chloride, triclosan or chlorhexidine digluconate, as well as zinc compounds such as zinc acetate, zinc gluconate, zinc oxide, zinc stearate and zinc salicylate. Additionally, the Examiner states that Modak discloses that benzalkonium chloride interacts synergistically with the antimicrobial agent parachlorometaxylenol (PCMX). The Examiner also alleges that Beilfuss describes a deodorant composition comprising octoxyglycerin (0.01-20%) and an antimicrobial (*e.g.* chlorhexidine salts) which exhibits a deodorizing effect through antimicrobial activity, inhibition of enzymes or catalysts responsible for odor formation, and inhibition of sweat secretion. The Examiner further states that Beilfuss' formulations are effective antimicrobials against gram positive and gram negative microorganisms, and that combining glycerin monoalkyl ethers with other antimicrobial agents results in synergistic antimicrobial effects. According to the Examiner, it would have been obvious to a skilled artisan to combine the antimicrobial agents described by the three references to produce the antimicrobial composition encompassed by the claims of the instant application.

Applicants respectfully disagree, and submit that evidence of unobvious or unexpected advantageous properties rebuts *prima facie* obviousness, and that the presence of a property not possessed by the prior art is sufficient evidence of nonobviousness. *See* M.P.E.P. 716.02(a); see also *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). The claimed invention encompasses, *inter*

*alia*, the unexpected discovery that octoxyglycerin can interact synergistically with different antimicrobial compounds, for example benzalkonium chloride or a biguanide, when combined together in a single formulation. Furthermore, as encompassed by new claims 3 and 4, Applicants have surprisingly and unexpectedly discovered that including a cationic emulsifier (*e.g.*, Incroquat) or a non-ionic self emulsifying wax (*e.g.*, Polawax) in an antimicrobial composition increased the antimicrobial effectiveness of the composition compared to art recognized compositions comprising the same antimicrobial agents.

In the previously filed response to the earlier office action, Applicants submitted that the surprising and unexpected results achieved by practicing the claimed invention are evidenced by the antimicrobially synergistic effect that can be produced by combining octoxyglycerin, a quaternary ammonium compound (*e.g.*, benzalkonium chloride) and a second antimicrobial agent (*e.g.*, chlorhexidine digluconate) together in a single composition, wherein the synergistic effect was greater than the additive effect of the each agents' independent antimicrobial activities. *See* Examples 3 and 4 of the instant application at pages 37-42.

Applicants further assert that the surprising and unexpected synergistic antimicrobial effect accomplished by practicing the claims is not only achieved by combining two antimicrobial agents together with octoxyglycerin in a single composition, but also by the interaction of octoxyglycerin with *each* of the two antimicrobial agents independently. For example, as described in Examples 1 and 2 (*see* pages 34-37), combining octoxyglycerin with either benzalkonium chloride or chlorhexidine gluconate produced an antimicrobially synergistic effect. Specifically, when octoxyglycerin was combined with benzalkonium chloride, the combination formulation exhibited a synergistic increase that was up to 2.3 log<sub>10</sub> greater than the independent additive effects of the two agents. *See* Table 2 at page 36. Similarly, when octoxyglycerin was combined with chlorhexidine digluconate, the combination formulation exhibited a synergistic antimicrobial effect that was up to 2.4 log<sub>10</sub> greater than the independent additive effects of the two agents. *See* Table 3 at page 37. Furthermore, octoxyglycerin's ability to synergistically increase the effectiveness of antimicrobial agents was not limited to benzalkonium chloride and chlorhexidine digluconate, but was also observed when it was combined with, for example, triclosan or povidone iodine. *See* Table 5 at page 40.

With regard to the Examiner's contention that Beilfuss discloses antimicrobially synergistic combinations of glycerin monoalkyl ethers (Sensiva) with other antimicrobial agents

(*see* Beilfuss at Col. 3, lines 39-41), and that Modak discloses a synergistic combination of benzalkonium chloride with parachlorometaxilenol (*see* Modak at Col. 3, lines 39-41), and further, combining such ingredients with the antimicrobial agents of Jampani produces a synergistic antimicrobial composition, Applicants respectfully disagree. First, even if Beilfuss described a synergistic effect between Sensiva and a second antimicrobial agent, which Applicants do not concede, Beilfuss provides no direction as to which antimicrobial agents Sensiva can allegedly interact synergistically with. The reference does not suggest or describe that Sensiva can synergistically increase the effectiveness of benzalkonium chloride or chlorhexidine gluconate, as disclosed by the instant application and discussed above, nor does the reference disclose that a quaternary ammonium compound (*i.e.*, benzalkonium chloride) could be used in combination with glycerin monoalkyl ethers as an antimicrobial “deo-active ingredient.” At best, Beilfuss provides a list of antimicrobial compounds from which a skilled artisan could blindly select, with no guidance from the reference, while at the same time disclosing that synergistic effects may only be “observed in some cases.” *See* Beilfuss at Col. 3, lines 13-42.

Secondly, with regard to Modak, Applicants note that although the reference may disclose that an “anti-microbial synergist” may be used to increase the efficacy of an antimicrobial agent beyond the additive effects of the agent and the synergist, the reference does not suggest or describe that octoxyglycerin is such a synergist that can increase the effectiveness of a quaternary ammonium compound (*e.g.*, benzalkonium chloride) or a biguanide (*e.g.*, chlorhexidine gluconate). Furthermore, although Modak specifically discloses synergists that may be used with chlorhexidine, it does not suggest or describe octoxyglycerin as such a synergist. *See, e.g.*, Modak at Col. 9, lines 13-30. Finally, with regard to Jampani, although the reference may disclose that antimicrobial agents may be useful in formulating topical compositions for controlling the proliferation of microorganisms, it provides no suggestion that such agents interact synergistically. Thus, the combined teaching of the cited references, while, for arguments sake, and not by way of concession, may disclose the various ingredients and elements of the present claims, does not suggest or describe that the elements can be combined to achieve the surprising and unexpected results demonstrated by the present invention, *i.e.*, that octoxyglycerin can synergistically increase the antimicrobial effectiveness of both a quaternary

ammonium compound (*e.g.*, benzalkonium chloride) and a second antimicrobial compound (*e.g.*, chlorhexidine gluconate).

Additionally, Applicants note that new claims 3 and 4 recite that the claimed composition further comprises a cationic emulsifier or a non-ionic self emulsifying wax (*e.g.*, Incroquat Behenyl TMS and Polawax, respectively, *see* the specification at page 20, paragraph 50). As described in Examples 13 and 14 (*see* pages 51-55), including such emulsifiers in an antimicrobial formulation comprising chlorhexidine or benzalkonium chloride produced a surprising and unexpected increase in the effectiveness of the antimicrobial agents as compared to art recognized compositions comprising the same antimicrobial agents (*i.e.*, Avagard and Prevacare). Specifically, when such emulsifiers were included in a composition comprising chlorhexidine, the emulsifiers increased the effectiveness of the antimicrobial agent, whereby microbial growth was reduced to a level as low as 240 cfu (“colony forming units”) compared to 1428 cfu for Avagard, which contained the same amount of chlorhexidine, but in combination with different emulsifiers. *See* the specification, tables 15, 16 and 17 at pages 53-54. Similarly, when a cationic emulsifier (*i.e.*, Incroquat) was added to an antimicrobial composition comprising benzalkonium chloride and phenoxyethanol, the emulsifier increased the effectiveness of the antimicrobial agents, whereby microbial growth was reduced to a level of 181 cfu compared to 1760 cfu for Prevacare, which contained the same amounts of benzalkonium chloride and phenoxyethanol, but in combination with different emulsifiers. *See* the specification, tables 15, 16 and 17 at pages 53-54.

In view of the surprising and unexpected increases in antimicrobial efficacy achieved by practicing the invention as claimed, Applicants submit that the claims are not obvious in view of the collective teaching of the cited references. Thus, Applicants respectfully request that the rejection be withdrawn.

## **II. The Double Patenting rejection**

The Examiner has rejected claims 1 and 2 on the ground of nonstatutory obviousness-type double patenting as double-patenting over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 (“the ‘846 patent”). The Examiner contends that the ‘846 patent is directed to an antimicrobial composition comprising synergistic effective amounts of octoxyglycerin, a quaternary ammonium compound, and an antimicrobial compound selected from a biguanide,

triclosan, phenoxyethanol, an iodine compound and parachlorometaxylenol. According to the Examiner, the claims of the instant application are not patentably distinct over the claims of the '846 patent.

Without conceding to the Examiner's contentions, Applicants respectfully submit that the appropriate action will be taken (*e.g.*, through the submission of a Terminal Disclaimer), upon withdrawal of the rejection under 35 U.S.C. § 103(a).

### **III. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and the rejections withdrawn. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe no fee in addition to the fee associated with the Request for Continued Examination submitted herewith is due. However, if any other fees are required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit any overpayments made, to Deposit Account 02-4377.

Respectfully submitted,

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